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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,588	09/15/2003	Sven Schreder	MERCK-2168D1	8058
23599 7590 08/13/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER SPIVACK, PHYLLIS G	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 08/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/661,588

**Applicant(s)**

SCHREDER ET AL.

**Examiner**

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 3-6 is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicants' Amendment and Terminal Disclaimer filed June 6, 2007 are acknowledged. Claims 1, 3-6 and 9-16 remain under consideration.

Applicants' arguments have been fully considered and are persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejection is newly applied. It constitutes the only rejection presently applied to the instant claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds et al., U.S. Patent 3,808,332, in view of Lindenbaum, E. al., WO 93/04691.

Reynolds teaches a combination of L-thyroxine and L-triiodothyronine that are physically admixed. Therefore, no organic solvent residues are present. See column 7, lines 65-67. See Composition I, column 7, where cornstarch is employed as a filler, and Composition J, where lactose and microcrystalline cellulose are employed as fillers. As required by instant claim 3, Reynolds teaches a concentration range of L-thyroxine of 100-300 mcg. Fillers such as lactose, maize starch and microcrystalline cellulose are conventional excipients. Reynolds fails to include gelatin in the combination. However, Lindenbaum teaches pharmaceutical preparations comprising levothyroxine or triiodothyronine and gelatin that are manufactured in solid forms, such as creams or powders, without organic solvents. See claims 13 and 19, as well as page 17, lines 16-

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18. A micronized form of levothyroxine with a particle size between 5 and 25  $\mu\text{m}$  is conventional.

Therefore, in view of the combined teachings of Reynolds and Lindenbaum, one skilled in the art of formulation chemistry would have been motivated to prepare pharmaceutical formulations comprising L-thyroxine and, optionally, triiodothyronine, utilizing gelatin, in a solid form without organic solvents. Further, if Applicants contend that the additional material in the prior art, e.g., potassium iodide, is excluded by the recitation "consisting essentially of," Applicants have the burden of showing that the additional component would materially change the characteristics of Applicants' invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Schreder et al., U.S. Patent 6,491,946, is provided as evidence that pharmaceutical preparations comprising a micronized form of levothyroxine have a particle size between 5 and 25  $\mu\text{m}$ . See column 2, lines 15-21.

Claims 1 and 3-6 appear to be free of the prior art.

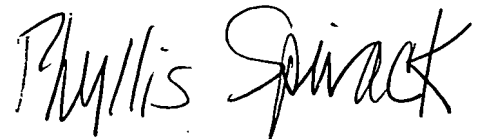
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 7, 2007



Phyllis G. Spivack

1614 **PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**